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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,408	05/17/2005	Thomas P. Quinn	UVMO:023US/10412756	2719
32425 7590 01/08/2008 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE.			EXAMINER HOLLERAN, ANNE L	
	1643			
			MAIL DATE	DELIVERY MODE
: •			01/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/520,408	QUINN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Anne L. Holleran	1643				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will; by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	L. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 29 October 2007.						
· _ ·						
3) Since this application is in condition for allowan	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	•					
4) ⊠ Claim(s) <u>1-20</u> is/are pending in the application. 4a) Of the above claim(s) <u>5 and 6</u> is/are withdra 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-4 and 7-20</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or						
Application Papers		·				
9) The specification is objected to by the Examiner	· f.					
10) ☐ The drawing(s) filed onis/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correcting 11) The oath or declaration is objected to by the Example 11.	, , , , , ,	·				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
AMachananta)	ì					
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) D Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	te				
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	5)  Notice of Informal P	atent Application				

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## **DETAILED ACTION**

#### Election/Restrictions

1. The amendment filed 10/29/2007 is acknowledged.

2. Claims 1-20 are pending. Claims 5 and 6, drawn to non-elected inventions, are withdrawn from consideration.

# Claim Rejections/Objections Withdrawn:

# **Objections**

3. The objection to the specification on the grounds that this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) and fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the sequence "KCCYSL" does not have a sequence identifier in the claims is withdrawn in view of the amendment to claim 1.

## Claim Rejections - 35 USC § 102

4. The rejection of claims 1, 2, and 7-13 under 35 U.S.C. 102(a) as being anticipated by Karasseva (Karasseva, N.G. et al., Journal of Protein Chemistry, 21(4): 287-296, 2002, May) is withdraw in view of the declaration filed under 37 C.F.R. 1.132 showing that the inventorship of Karasseva is the same as that of the instant invention.

## Claim Rejections - 35 USC § 103

5. The rejection of claims 1-4, and 7-20 under 35 U.S.C. 103(a) as being unpatentable over Karasseva (supra) in view of Thakur (Thakur, M.L. et al., J. Nuclear Medicine, 41: 107-110,

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2000) and further in view of Langer (Langer, M. et al. Curr. Med. Chem., Anti-Cancer Agents, 1: 71-93, 2001) is withdrawn in light of the declaration showing that the inventorship of Karasseva is the same as that of the instant invention.

# Claim Rejections Maintained:

# Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 and 7-20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is that the specification fails to adequately support a genus of peptides that comprise the sequence KCCYSL.

Applicants' arguments have been carefully considered but fail to persuade. Applicants argue that the examiner's rejection is based on three issues;, that applicants have only exemplified a targeting construct of KCCYSL, that the claims encompass peptides up to 100 residues, and the extraneous residues attaches to KCCYSL might block the access of KCCYSL to its target or otherwise hinder its function. Applicants state that the examiner has not properly applied the controlling legal precedent to the fact of the present situation, and that the claims to not lack structural definition, and that one of skill in the art can immediately appreciate that a

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given peptide may be lined to other sequences for a variety of purposes. Applicants also provide a declaration demonstrating that KCCYSL may be linked to a radiometal chelator. The arguments provided by applicants as well as the declaration do not address the full scope of the genus which is that the peptides may be quite large in structure compared to the small binding motif, and that the peptide itself, not merely the motif, is what is attached to the agent.

Therefore, the genus of peptides has not been adequately described. Applicants may wish to consider an amendment that adds a functional limitation that indicates that that the peptide comprising the motif is able to bind to ErbB2. Such an amendment, provided there is support in the specification as originally filed, may obviate the rejection of record.

## Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The

examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry

Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the

status of this application or proceeding should be directed to the Group receptionist whose

telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile

transmission. The faxing of such papers must conform to the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571)

273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran Patent Examiner

PRIMARY EXAMINE